Remarks

Reconsideration of the captioned application as amended herewith and in view of the following Remarks and Arguments is respectfully requested.

I. Status of the Claims

Claims 1 - 3, 5, 6, and 9 - 15 are pending in the application. Claim 1 has been amended to further define the amount of the redness or inflammation reducing agent. Support for the amendment to claim 1 can be found in the specification at least at page 3, lines 25-28.

II. Response to Rejections

Claims 1 – 5 are not anticipated under 35 U.S.C. §102 (a) and (e) by U.S. Patent No.6,365,623 ("the '623 patent").

The Examiner has rejected claims 1-3 and 5 under 35 U.S.C. §102 (a) and (e) as allegedly anticipated by the '623 patent. Applicants respectfully request withdrawal of this rejection.

Claims 1 –3 and 5 relate to a method for **ameliorating redness or inflammation of mammalian skin**. The method comprises the step of topically applying a composition **to red or inflamed mammalian skin**, where the composition comprises:

(a) from about 1.0 to about 10% by weight, based on the total composition, of a redness or inflammation reducing agent selected from an alkanolamine, tyrosine; or a mixture thereof; and

(b) a cosmetically acceptable carrier.

In contrast, the '623 patent relates to a method for reducing and preventing acneform scars and reducing pore size. The method comprises topically applying to affected skin areas a composition containing lipoic acid or a lipoic acid derivative in a dermatologically acceptable carrier. The composition of the '623 patent may include

adjunct ingredients. The disclosure of the '623 patent includes dimethylaminoethanol and tyrosine in a broad list of adjunct ingredients (column 5, lines 38 – 46). The Examiner argues that because the '623 patent teaches the inclusion of dimethylaminoethanol and tyrosine as adjunct ingredients, the '623 patent anticipates the present claims. Appellants respectfully disagree.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.wd 628, 631, 2 USPW2d 1051, 1053 (Fed. Cir. 1987). Here, the '623 patent fails to anticipate the claimed invention because the '623 patent fails to disclose a method for ameliorating redness or inflammation of mammalian skin, comprising the step of topically applying to red or inflamed mammalian skin a composition comprising

(a) from about 0.1 to about 10% by weight, based on the total composition, of a redness or inflammation reducing agent selected from an alkanolamine, tyrosine; or a mixture thereof; and

(b) a cosmetically acceptable carrier.

Further, even assuming *arguendo* that the '623 patent teaches a method for ameliorating redness or inflammation of mammalian skin, one of ordinary skill in the art certainly would not incorporate the alkanolamine and tyrosine adjunct ingredients taught by the '623 patent for use in such a method. Indeed, most of the compounds included in the list of adjunct ingredients of the '623 patent (ie. alpha-hydroxy acids, retinoids, etc.) are known to those of ordinary skill in the art to be skin irritants. Skin irritants would be expected to redden or inflame the skin, not reduce redness or inflammation. In fact, dimethylaminoethanol is taught to be corrosive to the skin and causes severe eye damage in animals (see paragraph 3.2.3 of the Risk Assessment document previously submitted). The Risk Assessment document states that dimethylaminoethanol is expected to show similar corrosive effects on the skin and eyes of humans. Applicants have surprisingly found that tyrosine and ethyl-aminoalcohols have anti-inflammatory properties and function to reduce redness on mammalian skin. Applicants respectfully submit that the rejection under 35 U.S.C.

§102 (a) and (e) with respect to the '623 patent is clearly erroneous and respectfully request withdrawal of the rejection.

Claims 1 – 3 and 5 are not anticipated under 35 U.S.C. §102 (a) and (e) by U.S. Patent No. 6,319,942 ("the '942 patent").

The Examiner has rejected claims 1-3 and 5 as allegedly anticipated by the '942 patent. The '942 patent relates to methods for the treatment or inhibition of cutaneous scar tissue. There is no teaching or suggestion of a method for ameliorating redness or inflammation of skin. The Examiner argues that Perricone '942 teaches that the formation of scars undergo inflammatory stage and that hypertrophic and keloid scars show inflammatory activity. The fact that some stages or some scars undergo an inflammatory stage is irrelevant to Applicants claimed method for ameliorating redness or inflammation of mammalian skin. Furthermore, the '942 patent teaches that the compositions of that invention prevent cross-linking of cell membranes to reduce keloid scar formation (column 7, lines 56 – 62) and prevent incessant membrane damage (column 8, lines 14 – 20). Clearly, the '942 patent specifically relates to the treatment of cutaneous scar tissue not red or inflamed skin as in Applicants claimed invention. Accordingly, Applicants respectfully submit that Perricone '942 cannot anticipate the present claims.

Further, the '942 patent fails to teach or suggest the combination of actives selected by the present inventors. As was the case with the '623 patent, the '942 patent lists adjunct ingredients (ie. alpha-hydroxy acids, retinoids, etc.), most of which are known to those of ordinary skill in the art to be skin irritants. One of ordinary skill in the art would not have been motivated to incorporate skin irritants into a composition to be used for ameloriating redness or inflammation of skin. Clearly, such a composition would be expected to redden or inflame the skin. In contrast, Applicants have surprisingly found that tyrosine and alkanolamines have anti-inflammatory properties and function to reduce redness on mammalian skin. Applicants respectfully submit that the rejection under 35 U.S.C. §102 (a) and (e) with respect to the '942 patent is clearly incorrect and respectfully request withdrawal of the rejection.

Claims 1, 2, and 10 are not anticipated under 35 U.S.C. §102 (a) and (e) by Ptchelintsev (US 5972993) ("'993").

Claims 1, 2, and 10 stand rejected as anticipated by the '993 patent. The Examiner argues that the '993 patent teaches the use of triethanolamine to reduce redness. Applicants respectfully submit that the Examiner has misinterpreted the teachings of the '993 patent. The '993 patent specifically teaches that antioxidants function to treat rosacea (column 4, lines 35 – 38). Suitable antioxidants are listed in column 4, lines 41 – 65. Triethanolamine is not an antioxidant, nor is it listed in the materials that are useful to treat rosacea. The Example cited by the Examiner (column 10, lines 33 – 36) and any other Example of the '993 patent containing triethanolamine also contain tocopherol and lycopene (antioxidants), or other antioxidants. Further, the triethanolamine is present at 0.5% which is well below the amount of alkanolamine or tyrosine recited by amended claim 1.

There is no teaching or suggestion in the '993 patent to reduce redness or inflammation utilizing the compositions of the present invention. Applicants respectfully submit that the rejection under 35 U.S.C. §102 (a) and (e) with respect to the '993 patent is without merit and respectfully request withdrawal of the rejection.

Claims 6 and 9 – 15 are not unpatentable under 35 U.S.C. §103(a) over the '942 patent as applied to claims 1 – 3 and 5, further in view of De Lacharriere et al. (US 5968532) ("the '532 patent").

Claims 6 and 9 – 15 stand rejected under 35 U.S.C. §103 (a) as unpatentable over the '942 patent in view of the '532 patent.

Claim 6 relates to a method according to claim 1, wherein said composition further comprises a skin irritating ingredient selected from a retinoid, benzyol peroxide, alpha - hydroxyacids and derivatives thereof, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives, urea, preservatives.

Claim 9 relates to a method for ameliorating redness or inflammation of mammalian skin as recited in claim 1, wherein the composition is applied to sun burned skin, wind burned skin or skin that is red or inflamed due to contact with irritating soaps or cleansers. Claim 10 relates to a method according to claim 1, wherein the composition is applied to skin that is red or inflamed due to rosacea, atopic dermatitis or allergic skin reactions.

Claims 11-15 relate to a method for ameliorating the irritating effects of a skin irritating composition comprising adding to said composition an effective amount of a compound selected from the group consisting of an alkanolamine; tyrosine; or a mixture thereof wherein said skin irritating compositions comprises at least one compound selected from retinoid, benzyol peroxide, alpha-hydroxyacids and derivatives thereof, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives, urea, and preservatives.

As discussed above, the '942 patent relates to a method for or the treatment or inhibition of cutaneous scar tissue comprising applying to said tissue a composition containing an effective amount of an alkanolamine. The Examiner recognizes that the '942 patent "fails to teach treating redness or inflammation caused by the irritants recited in the instant claims." The Examiner then relies upon the '532 patent to cure these deficiencies of the '942 patent.

As discussed above, the '942 patent relates to the treatment of **scar tissue**. Scar tissue whether inflamed or not is not the same as red or inflamed skin. On the other hand, the '532 patent relates to the use of an ethylenediamine derivative as a substance P antagonist and /or as a local analgesic in, or for the preparation of, a cosmetic or dermatological composition for treating sensitive skin types. There is no teaching or suggestion in the '532 patent that compositions useful for treating scars could also be used for treating red or inflamed skin.

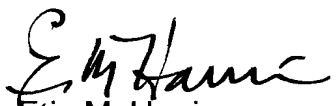
The Examiner argues that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of treating scars or inflamed skin condition described in Perricone '942 by applying the composition therein to the reddened or inflamed skin caused by the irritants or damaged by environment as motivated by de Lacharriere." Applicants respectfully submit that the '532 patent fails to provide any motivation to modify the method taught by the '942 patent. Simply because the '532 patent teaches a method for treating sensitive skin types does not provide the requisite motivation for expanding the methods taught by the '942 patent to include the treatment of red or inflamed skin. The Examiner also argues that "the skilled artisan would have expected that the composition that is effective in treating inflammatory scar wounds would be similarly effective in reducing inflammation or the associated symptoms caused by other factors such as skin irritants." Again, Applicants respectfully disagree. Scar tissue whether inflamed or not is different from red or inflamed skin. The fact that a composition is useful for reducing scars does not mean that the same composition would be effective for treating red or inflamed skin. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and the rejection should be withdrawn.

In summary, the '532 patent does nothing to make up for the deficiencies in the teachings of the '942 patent. The '532 patent does not teach the compounds utilized in the present invention, nor does it teach the use of the compounds of the present invention to ameliorate redness or inflammation. Furthermore, there is no teaching or suggestion in the references to modify the methods taught by the '942 patent. Applicants respectfully submit that the combination of the references does not provide the present invention. Applicants therefore respectfully request withdrawal of the rejection.

Conclusion

Applicants believe that the foregoing presents a full and complete response to the present Office Action. Applicants believe that this Response places the case in condition for allowance. If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP-525/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,



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